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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,175	07/11/2001	Hau H. Doung	A-68718-3/RFT/RMS/RMK	1169

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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	10

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,175	DOUNG ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, Claims 1-9 in Paper No. 9 is acknowledged.

Applicant's cancellation of non-elected Claims 10-23 in Paper No. 9 is acknowledged.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional applications 60/145,840 and 60/175,539 upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-9 of this application.

The first paragraph of the specification and the filing receipt incorrectly claim benefit of provisional application 60/145,840. The declaration correctly claims benefit of provisional application 60/245,840. Appropriate correction is required.

Provisional application 60/175,539 fails to provide support for the instantly claimed biochip cartridge. Claims 1-9 are drawn to a biochip cartridge comprising a substrate comprising an array of electrodes, each comprising a self-assembled monolayer and a capture binding ligand. The '539 application provides a general discussion of biochips in a cartridge, but the application does not teach or describe the instantly claimed substrate comprising an array of electrodes, each comprising a self-assembled monolayer and a capture binding ligand. Therefore, the provisional applications upon which priority is claimed fails to provide adequate

support under 35 U.S.C. 112 for claims 1-9 of the instant application. Because the provisional applications fail to provide support for the instant claims, the effective filing date for instant claims 1-9 is the filing date of parent applications 09/760,384 and PCT/US01/01150 i.e. 01/11/2001.

Information Disclosure Statement

3. The references listed on the 1449 received 27 August 2001, 25 January 2002, and 1 August 2002 have been reviewed and considered. Additionally, the International Search Report has been considered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application

designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Wohlstadter et al (WO 98/12539, published 26 March 1998).

Regarding Claim 1, Wohlstadter et al disclose a biochip cartridge comprising a reaction chamber and interconnects to allow electrical connection of electrodes to a processor, the reaction chamber comprising a substrate and an inlet port (page 17, line 29-page 19, line 3) and the substrate comprising an array of electrodes each comprising a self-assembled monolayer and a capture binding ligand (page 23, lines 1-9).

Regarding Claim 2, Wohlstadter et al disclose the biochip wherein the capture binding ligands are capture probes e.g. bio-specific binding partner (page 18, line 37-page 19, line 3).

Regarding Claim 3, Wohlstadter et al disclose the biochip wherein said reaction chamber further comprises a gasket to retain fluid in contact with said array i.e. compression means removable placed on opposite sides of the two supports (page 81, lines 29-32) and o-rings which define the active area (e.g. page 196, lines 18-22 and page 197, last paragraph).

Regarding Claim 5, Wohlstadter et al disclose the biochip further comprising an outlet port i.e. fluid channel (#184) traversing the cassette (page 18, lines 15-22 and Fig. 1).

Regarding Claim 7, Wohlstadter et al disclose the biochip wherein said array is on one surface of said substrate (page 8, line 36-page 9, line 11; page 78, line 16-page 79, line 13; and Fig. 2-3).

6. Claims 1, 2 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Kayyem , J. (WO 00/62931, published 26 October 2000).

Regarding Claim 1, Kayyem discloses a biochip cartridge comprising a reaction chamber and a interconnects to allow electrical connection of electrodes to a processor, the reaction chamber comprising a substrate and an inlet port (page 2, lines 17-26) and the substrate comprising an array of electrodes each comprising a self-assembled monolayer and a capture binding ligand (page 43, lines 3-35).

Regarding Claim 2, Kayyem discloses a the biochip wherein the capture binding ligands are capture probes (page 12, line 12-page 14, line 7).

Regarding Claim 9, Kayyem discloses the biochip further comprising a cap comprising at least one storage well comprising assay reagents (page 2, lines 4-15 and Fig. 1).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 4, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al (WO 98/12539, published 26 March 1998) in view of Schembri et al (U.S. Patent No. 6,258,593, filed 30 June 1999).

Regarding Claim 4, Wohlstadter et al teach a biochip cartridge comprising a reaction chamber and interconnects to allow electrical connection of electrodes to a processor, the reaction chamber comprising a substrate and an inlet port (page 17, line 29-page 19, line 3) and the substrate comprising an array of electrodes each comprising a self-assembled

monolayer and a capture binding ligand (page 23, lines 1-9) but they do not teach the inlet port comprises a seal. However, biochip cartridges having sealed inlet ports were well known in the art at the time the claimed invention was made as taught by Schembri et al.

Schembri et al teach a similar biochip cartridge comprising a reaction chamber and comprising a substrate and an inlet port wherein the substrate comprises a monolayer and a capture binding ligand (Column 4, line 55-Column 5, line 9 and Fig. 1) and further comprising a seal on said inlet port i.e. the inlet port (Fig. 2, #10) is integral with the cover which comprises a seal (Column 11, lines 9-37) thereby providing a sealed reaction chamber. Schembri et al teach that their sealed chamber facilitates reagent mixing, reduces the occurrence of unwanted reactions, prevents drying of reagents even at high temperatures, and can be readily assembled, taken apart and reused (Column 4, lines 27-37). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cartridge inlet of Wohlstadter et al by providing a seal on the inlet port to thereby provide a sealed reaction chamber as taught by Schembri et al for the expected benefits of facilitating reagent mixing, reducing the occurrence of unwanted reactions and preventing drying of reagents even at high temperatures in a chamber which is readily assembled, taken apart and reused as taught by Schembri et al (Column 4, lines 27-37).

Regarding Claim 6, Wohlstadter et al do not teach the reaction chamber is configured to minimize introduction or retention of air bubbles. However, Schembri et al teach the similar chamber wherein the chamber is configured to control the presence of a bubble within the chamber wherein the bubble facilitates and improves mixing within the chamber (Column 12, lines 25-42) and taking "care to leave a small bubble of air" in the chamber (Column 17, lines4-8) and hence minimize introduction of additional air bubbles.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the bubble and bubble control of Schembri et al the reaction

chamber of Wohlstadter et al for the expected benefit of improving and facilitating reagent mixing as taught by Schembri et al (Column 12, lines 25-42).

Regarding Claim 8, Wohlstadter et al teach the biochip wherein one surface comprises an array (Fig. 1-3). Schembri et al teach the similar biochip wherein each of two surfaces of the substrate comprise an array (Fig. 1) whereby multiple arrays are formed thereby providing for multiple assays (Column 11, lines 25-37).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the substrate surface of Wohlstadter et al with the two array surfaces as taught by Schembri et al for the expected benefit of providing for multiple assays within a single cartridge as taught by Schembri et al (Column 11, lines 25-37).

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al (WO 98/12539, published 26 March 1998) in view of Anderson et al (U.S. Patent No. 6,326,211, filed 27 June 1996).

Regarding Claim 9, Wohlstadter et al teach a biochip cartridge comprising a reaction chamber and interconnects to allow electrical connection of electrodes to a processor, the reaction chamber comprising a substrate and an inlet port (page 17, line 29-page 19, line 3) and the substrate comprising an array of electrodes each comprising a self-assembled monolayer and a capture binding ligand (page 23, lines 1-9) wherein the cartridge comprises means for introducing reagents into the cartridge (page 18, lines 15-22) but they do not teach means includes a storage well in the cap. However, means for introducing reagents into a cartridge comprising a storage well in a cartridge cap was known in the art at the time the claimed invention was made as taught by Anderson et al.

Anderson et al teach a similar cartridge comprising a reaction chamber and interconnects, the reaction chamber comprising a substrate and an inlet port and electrodes wherein the substrate comprises a capture binding ligand (Column 2, line 22-51) and further comprising means for introducing reagents into the cartridge wherein the means comprises a cap (well #510 illustrated in the top portion of the cartridge illustrated in Fig. 5B) comprising at least one storage well comprising assay reagents (Column 24, lines 44-65 and Fig. 5 A & B) wherein the arrangement of storage wells adjacent to the substrate provides easy access to reagents and convenient storage reagents (Column 25, lines 42-52).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the cap comprising a storage well as taught by Anderson et al to the cartridge of Wohlstadter et al for the expected benefits of easy access to reagents and convenient storage reagents as taught by Anderson et al (Column 25, lines 42-52).

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
December 20, 2002